UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

Christopher T. Dahl,

Plaintiff,

v.

Civ. No. 07-192 (JNE/SRN)
ORDER

Atritech, Inc., a Delaware corporation doing business as Atritech, Inc., a Minnesota foreign corporation,

Defendant.

Teresa McClain, Esq., and Kristi Lemieux, Esq., Hallberg & McClain, P.A., appeared for Plaintiff Christopher T. Dahl.

Roseann J. Bour, Esq., and George Soule, Esq., Bowman and Brooke LLP, appeared for Defendant Atritech, Inc.

Christopher T. Dahl brings this action to recover damages for injuries he sustained when complications arose during implantation of an experimental medical device in his heart. Dahl asserts claims of negligent design, manufacture, and sale; strict liability for design, manufacture, and sale of an unreasonably dangerous and defective product; and breach of express and implied warranties. The case is before the Court on Atritech, Inc.'s Motion for Summary Judgment. For the reasons stated below, the Court denies Atritech's motion.

I. BACKGROUND

Dahl, who has a history of heart-related medical problems, agreed to participate in a clinical trial of Atritech's WATCHMAN Left Atrial Appendage Filter System. The WATCHMAN device is designed to be placed over the left atrial appendage, a pouch-like area inside the heart, and it is intended to prevent blood clots formed in left atrial appendage from entering the blood stream, thereby reducing the risk of stroke and obviating the need for anti-

clotting medication like Coumadin. In 2004, the WATCHMAN device was considered to be an investigational device, meaning it could be studied in clinical trials but had not yet been fully approved by the FDA.

Prior to undergoing the procedure to implant the WATCHMAN device, Dahl signed Atritech's informed consent form,[1] indicating that he understood its terms. The form indicates that the WATCHMAN device is experimental, and it states that the goals of the clinical trial "are to determine whether the WATCHMAN™ device can be safely implanted and to assess the safety of the device over the early follow-up period." However, the form also delineates elements of use and implantation of the WATCHMAN device that are not experimental, asserting that "[t]he only experimental part of this research study is the use of the WATCHMAN™ device" and that "[t]he methods used during the procedure are well known and other methods have been used previously to close the left atrial appendage." Regarding the WATCHMAN device itself, the form states "[t]he WATCHMAN™ is made of materials that are common to many medical devices."

The informed consent form lists many risks that are associated with participation in the study:

> [The risks associated with the use of the WATCHMAN device] include those typically related to any surgical procedure, those typically related to similar types of procedures performed in the heart, and those that are unique to the use of the WATCHMAN device.
>
> The risks typically related to any surgical procedure include: blood clots or air bubbles to the lungs or other parts of the body, heart attack, stroke, anesthetic problems, bleeding problems, infection and death.
>
> The risks typically related to similar types of procedures performed in the heart include: . . . an accidental hole punctured in your heart . . . .

[1] Dahl signed a second, less-detailed informed consent form with Abbott Northwestern Hospital.

> The risks associated with implanting the WATCHMAN device include: misplacement of the device, movement of the device in your heart or embolization into the aorta, the inability to place the device in the correct position or [inability] to remove the device if necessary, device fracture, . . . pain from improperly sized and/or placed device, . . . the potential of death, bleeding, infection, blood clot formation on the device, damage to the heart, blood vessels or heart valves, additional surgery if the device is not placed in the correct position.

The form also notes some complications that arose in a European clinical trial and states that "[d]ue to the investigational nature of this study, there may be other potential risks that are not currently known."

The form requires study participants "to return for follow-up exams so [doctors] can check the status of the device," noting that "[f]or the purposes of this research, it is very important that you return for each exam." The form states that "the protocol" requires patient involvement for at least one year, though patients "may be asked to continue to come back for doctor visits at annual intervals until enough information on the WATCHMAN^{TM} device has been collected in order to receive the necessary regulatory approvals. This study could last three years." However, the form also states that participants may withdraw from the study at any time before or after surgery.

Regarding monetary matters, the form indicates that Atritech will provide the WATCHMAN device at no cost, though the costs of implantation and follow-up care must be borne by the patient. The form states that "[p]atients will not be compensated for participating in this research." Finally, the form asserts that Atritech "does not intend to offer any payments for injuries or hospitalization that may occur as a result of your participation in this study."

On February 10, 2004, Dahl underwent surgery to implant the WATCHMAN device. After Dahl was sedated, the doctor inserted the WATCHMAN device into a vein in Dahl's groin

and then used a wire delivery tool to maneuver it into position inside Dahl's heart. Per Atritech's WATCHMAN device protocols, the doctor rotated the wire three times, which should have been sufficient to cause the WATCHMAN device to detach from the wire. However, the device did not detach, and the doctor was able to detect tension in the wire. After discussing the situation with two Atritech representatives, the doctor turned the wire an additional 360 degrees, and the wire broke. Open-heart surgery was required to remove the WATCHMAN device and fragments of the wire delivery tool. Dahl filed the present action seeking recovery for injuries he sustained as a result of the failed implantation procedure.

II. DISCUSSION

Summary judgment is proper "if the pleadings, the discovery and disclosure materials on file, and any affidavits show that there is no genuine issue as to any material fact and that the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(c). The movant "bears the initial responsibility of informing the district court of the basis for its motion," and must identify "those portions of [the record] which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). If the movant satisfies its burden, the party opposing the motion must respond by submitting evidentiary materials that "set out specific facts showing a genuine issue for trial." Fed. R. Civ. P. 56(e)(2); *see Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986). In determining whether summary judgment is appropriate, a court must look at the record and any inferences to be drawn from it in the light most favorable to the party opposing the motion. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986).

Primary assumption of risk

Atritech argues that Dahl's negligence and strict liability claims should be dismissed because Dahl expressly and primarily assumed the risk of the injury of which he now complains. When a plaintiff primarily assumes a risk, the plaintiff "consents to look out for himself," "the defendant has no duty to protect the plaintiff" from the risk the plaintiff has assumed, and the plaintiff is completely barred from recovering damages related to that risk. *Schneider v. Erickson*, 654 N.W.2d 144, 148 (Minn. Ct. App. 2002).

Primary assumption of risk applies "when a party voluntarily enters into a relationship in which the plaintiff assumes well-known, incidental risks." *Id*.; *see also Andren v. White-Rodgers Co.*, 465 N.W.2d 102, 105 (Minn. Ct. App. 1991) (applying assumption of risk doctrine to a strict products liability case). To establish primary assumption of a risk, it must be shown that the plaintiff had knowledge of the risk, appreciated the risk, and decided to take the risk despite an option to avoid it. *Schneider*, 654 N.W.2d at 149. In addition, it must be demonstrated that the plaintiff expressly or impliedly manifested consent to relieve the defendant of a duty that the defendant owed to the plaintiff. *Id*. at 150. "Minnesota courts rarely apply primary assumption of risk, and have found that its application is only appropriate under limited circumstances." *Id*. at 149; *see also Armstrong v. Mailand*, 284 N.W.2d 343, 350 (Minn. 1979) (holding that firefighters assume all risks that are "apparent to them that are a part of firefighting"); *Sandstrom v. AAD Temple Bldg. Ass'n*, 127 N.W.2d 173, 176 (Minn. 1964) ("[T]he licensee assumes the risk of defective conditions on property unknown to the possessor."); *Brisson v. Minneapolis Baseball & Athletic Ass'n*, 240 N.W. 903, 904 (Minn. 1932) (holding that spectator at baseball game assumed the risk of being hit by foul ball); *Snilsberg v. Lake Wash. Club*, 614 N.W.2d 738, 746 (Minn. Ct. App. 2000) (holding that a swimmer assumes the risk inherent in diving into

water of indeterminable depth). "Whether a party has primarily assumed the risk is usually a question for the jury, unless the evidence is conclusive." *Schneider*, 654 N.W.2d at 148.

To demonstrate that Dahl assumed risk of his injuries, Atritech points to the portions of the informed consent form that discuss "device fracture," "additional surgery," "potential unknown risks," Atritech's intention not to pay for injuries, and the WATCHMAN device's investigational or experimental nature. However, none of these passages conclusively establish Dahl's consent to the risks of negligence and product defect. *Cf.* 21 C.F.R. § 50.20 (2007) ("No informed consent . . . may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence."). By acknowledging that certain complications might result from participation in the clinical trial, Dahl did not conclusively release Atritech from all duties of care or consent that those complications might be brought about by any cause. *See Iepson v. Noren*, 308 N.W.2d 812, 815 (Minn. 1981) ("It is not every deliberate encountering of a known danger which is reasonably to be interpreted as evidence of [consent to relieve a defendant of the duty of reasonable conduct.]" (quotation omitted)); *Bakhos v. Driver*, 275 N.W.2d 594, 595 (Minn. 1979) (indicating that one does not necessarily assume the risk of others' negligence by undertaking an inherently dangerous act). Unlike a spectator at a baseball game who can watch for foul balls or a firefighter who is able to watch for hazards, Dahl was unconscious and unable to look out for himself at the time the injury occurred, and there is no evidence that Dahl possessed the means or the expertise to protect himself by examining the WATCHMAN device that was to be used in his procedure. *See Armstrong*, 284 N.W.2d at 350; *Brisson*, 240 N.W. at 904. These circumstances constitute evidence that Dahl did not consent to take full

responsibility for his safety. *Cf. Iepson*, 308 N.W.2d at 815-16 (stating that jaywalker who runs into traffic "does not manifest consent that they shall use no care and run him down" and is instead "insisting that they shall take immediate precautions for his safety" (quotation omitted)). Moreover, while Dahl may have assumed the ordinary risks involved with implantation of an experimental medical device, Atritech makes no argument either about the scope of its remaining duty of care (other than to deny that it exists) or about whether it fulfilled that duty. *Cf. Johnson v. Zimmer*, Civ. No. 02-1328, 2004 WL 742038, at *7 (D. Minn. Mar. 31, 2004) (indicating that a plaintiff's consent to the ordinary risks associated with surgery and implantation of a non-experimental prosthetic device does not relieve the defendant "of the duty to design and manufacture a safe product or otherwise care for [the plaintiff's] safety"). Accordingly, Atritech fails to demonstrate that it is entitled to summary judgment under a primary assumption of risk rationale.

Warranty claims "merge" with strict liability claims

Atritech argues that claims for breach of implied warranty of merchantability merge with strict liability claims when personal injury is alleged. As support, Atritech cites *Westbrock v. Marshalltown Manufacturing Co.*, 473 N.W.2d 352 (Minn. Ct. App. 1991). *Westbrock* states that strict liability, negligence, and implied warranty remedies merge into a single products liability theory. *See id.* at 356. However, the authority *Westbrook* cites to support this statement does not establish any such legal principle. *See id.* (citing *Bilotta v. Kelley Co.*, 346 N.W.2d 616, 623 n.3, 624 (Minn. 1984)); *Bilotta*, 346 N.W.2d at 623-24 (failing to indicate that warranty claims merge into strict liability claims); *id.* at 625 (stating that an instruction on express warranty may be appropriate on retrial even though retrial will also involve a design defect claim). For this reason, the Eighth Circuit has declined to follow *Westbrock* on this issue. *See*

Piotrowski v. Southworth Prods. Corp., 15 F.3d 748, 751-752 (8th Cir. 1994) ("*Westbrock* . . . do[es] not appear to be [a] proper [reading] of *Bilotta*, at least insofar as the implied warranty of fitness theory is concerned. Therefore, we find it was not erroneous for the district court to submit the case to the jury on both strict liability and breach of implied warranty of fitness theories.").

Atritech also relies on *In re Shigellosis Litigation*, 647 N.W.2d 1 (Minn. Ct. App. 2002). *In re Shigellosis* indicates in dicta that it may be proper for a court to refuse to give a jury instruction on implied warranty of merchantability if a warranty instruction would be duplicative of an instruction on strict liability that is "stronger and broader under the case facts." *Id.* at 11-12; *see also Goblirsch v. W. Land Roller Co.*, 246 N.W.2d 687, 690 (Minn. 1976) (finding no prejudice in failure to instruct jury on both express and implied warranty theories because a "stronger and broader" strict liability instruction was given); *Cont'l Ins. Co. v. Loctite Corp.*, 352 N.W.2d 460, 463 (Minn. Ct. App. 1984) (stating, in addressing propriety of jury instructions, that in cases where "strict liability is the broader theory of recovery [implied warranties are] pre-empted"). Even assuming that summary judgment is appropriate when warranty claims "merge" with strict liability claims in this way, Atritech fails to establish merger because it makes no argument about the breadth and strength of Dahl's various claims.

Failure to pay for the WATCHMAN device

Atritech argues that Dahl's express and implied warranty claims must fail because warranty claims require a sale of goods. Atritech contends that in this case there was no sale because Dahl "paid nothing" for the WATCHMAN device.

Atritech cites no authority for the proposition that that one party to a sale must pay cash, and Atritech has not established that Dahl's participation in a clinical trial, which provided

Atritech with research information, cannot be considered payment in the sale of a WATCHMAN device. To the contrary, Minnesota's commercial code indicates that a sale involves payment of a "price," Minn. Stat. § 336.2-106(1) (2006), and specifically states that "[t]he price can be made payable in money or otherwise," *id*. § 336.2-304(1) (2006); *cf. Around the World Merchandisers, Inc. v. Rayovac Corp.*, 585 A.2d 437, 440 (N.J. Super. Ct. Law Div. 1990) ("Services may constitute the price of goods [under the New Jersey commercial code]."). Accordingly, Atritech fails to establish that Dahl paid nothing for the WATCHMAN device.

Existence of express warranties

Atritech argues that Dahl's express warranty claim must fail because he cannot demonstrate the existence of an express warranty. Minnesota Statutes § 336.2-313(1) states:

> Express warranties by the seller are created as follows:
>
> > (a) Any affirmation of fact or promise made by the seller to the buyer which relates to the goods and becomes part of the basis of the bargain creates an express warranty that the goods shall conform to the affirmation or promise.
> >
> > (b) Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description.

While Dahl stated in his deposition that he neither received nor relied on any written or oral warranties regarding the WATCHMAN device, Atritech's informed consent form makes affirmations of fact regarding the WATCHMAN device that can be reasonably construed as creating express warranties, *e.g.*, "[t]he WATCHMAN™ is made of materials that are common to many medical devices." Accordingly, Atritech is not entitled to summary judgment under the rationale that Dahl cannot establish an express warranty.

III. CONCLUSION

Based on the files, records, and proceedings herein, and for the reasons stated above, IT IS ORDERED THAT:

1. Atritech's Motion for Summary Judgment [Docket No. 16] is DENIED.

Dated: March 14, 2008

s/ Joan N. Ericksen
JOAN N. ERICKSEN
United States District Judge